

Notice of Allowability

Application No.

10/681,581

Examiner

Luke S. Wassum

Applicant(s)

SHOLL ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to preliminary amendment, filed 8 January 2004.
2. ☒ The allowed claim(s) is/are 11-24.
3. ☒ The drawings filed on 08 January 2004 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).


* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 08062004
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 08062004
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


Luke S. Wassum
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DETAILED ACTION

The Invention

1. The claimed invention is a food safety system providing a consumer risk distribution model, wherein a database containing data about the distribution network for various food product types, and wherein a modeling system models a contamination incident based on the data in the distribution database, the specific type of food product under study and other attributes specified by the user.

Priority

2. The Applicants' claim to domestic priority under 35 U.S.C. § 119(e), based on U.S. Provisional Applications 60/417,099, filed 8 October 2002, and 60/469,875, filed 12 May 2003, is acknowledged.

Information Disclosure Statement

3. The Applicants' Information Disclosure Statement, filed 6 August 2004, has been received and entered into the record. Since the Information Disclosure Statement complies with the provisions of MPEP § 609, the references cited therein have been considered by the examiner. See attached form PTO-1449.

EXAMINER'S AMENDMENT

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312.

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To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with attorney Z. Peter Sawicki on 6 August 2004 (amendment to claim 23) and 25 August 2004 (cancellation of claims 5-10).

The application has been amended as follows:

In the specification:

On page 2, line 25, please replace "During,preservation" with -- During preservation --.

On page 3, line 6, please replace "completely chemical and physical changes" with -- completely prevent chemical and physical changes --.

On page 3, line 7, please replace "-18□" with -- -18 degrees Celsius --.

In the claims:

Please cancel claims 5-10.

In claim 23, please replace the claim as follows:

-- A system adapted to model a product contamination incident, the system comprising:

a product distribution database containing distribution data related to a flow of products in a stream of commerce, the distribution data being related to particular products;

a modeling software system adapted to receive a selected contamination type and a selected product type, and to model a probable contamination incident distribution within a stream of commerce based on the distribution data and on the selected contamination type and the selected product type; and

a user interface adapted to display the distribution data to provide user interaction options to a user. --

The examiner notes that the amendment to claim 23 is merely to clarify the claimed invention, and is not intended to further limit the claims, nor was the amendment made in order to distinguish over a particular prior art reference.

Allowable Subject Matter

5. Claims 11-24 are allowed.
6. The present invention is directed to a food safety system providing a consumer risk distribution model, wherein a database containing data about the distribution network for various food product types, and wherein a modeling system models a contamination incident based on the data in the distribution database, the specific type of food product under study and other attributes specified by the user.

The closest prior art of record, FSIS[1] ("*Salmonella* Enteritidis Risk Assessment") teaches a risk assessment process which incorporates available data into a comprehensive quantitative model which characterizes the public health effects associated with the consumption of *Salmonella* Enteritidis-infected shell eggs and egg products (see page 1, Executive Summary, first paragraph). This model includes data on the distribution chain as incorporated in the Shell Egg Processing and Distribution Module and the Egg Products Processing & Distribution Module (see page 8, Introduction, first two paragraphs; see also the detailed disclosure of the Shell Egg Processing and Distribution Module, pages 77-114, and the detailed disclosure of the Egg Products Processing & Distribution Module, pages 115-147).

However, FSIS[1] fails to anticipate or render obvious the recited feature of receiving a response time value related to the expected amount of time before a health department is made aware of the contamination incident (claim 11), nor receiving a selected contamination type on which the probable contamination incident is to be modeled (claim 23).

Lammerding et al. ("Quantitative Risk Assessment: An Emerging Tool for Emerging Foodborne Pathogens") teaches a system for modeling the health risks from eating contaminated food, including the ability to manipulate various parameters such as pathogen prevalence and concentration in raw material, temperature abuse in transportation and retail, consumer cooking preference, infectious dose and size of susceptible populations (see page 4, fourth paragraph).

However, Lammerding et al. fails to anticipate or render obvious the recited feature of a model including a product distribution database wherein the distribution data is associated with

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specific product types, and wherein the model operates based on the specific distribution data associated with a selected product type, as in independent claims 11 and 23.

Also relevant is **Montanari et al.** (U.S. Patent 5,478,990), which teaches a method for tracking food products and/or food supplements to enable verification of product origination and to trace back to the source of pathogens.

However, **Montanari et al.** tracks specific food items by placing identifiers, such as bar codes, on the products, and fails to teach a modeling system including a product distribution database wherein the distribution data is associated with specific product types, and wherein the model operates based on the specific distribution data associated with a selected product type, as in independent claims 11 and 23.

These features, together with the other limitations of the independent claims are novel and non-obvious over the prior art of record. The dependent claims 12-22 and 24 being definite, enabled by the specification, and further limiting to the independent claim, are also allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Montanari et al. (U.S. Patent 5,478,990) teaches a method for tracking food products and/or food supplements to enable verification of product origination and to trace back to the source of pathogens.

Davis et al. (U.S. Patent 6,409,082) teaches a method of detecting designated products from a number of sources.

ICMSF ("Microorganisms in Foods, Vol. 4") teaches the application of the hazard analysis critical control point (HACCP) system to ensure microbiological safety and quality.

Zwietering et al. ("Modeling of Bacterial Growth as a Function of Temperature") teaches the suitability and usefulness of different models, either available from the literature or newly developed, in predicting the number of organisms as a function of temperature and time, including the lag time, specific growth rate and asymptote (growth yield) as a function of temperature.

Zwietering et al. ("A Decision Support System for Prediction of the Microbial Spoilage in Foods") teaches a method for combining qualitative and quantitative information to predict possible growth of microorganisms in foods.

Gorris et al. ("The Food Micromodel for Prediction of Growth of Foodborne Pathogens") teaches a computer model for prediction of the survival, growth and death of foodborne pathogens in relation to temperature, pH, salt (or saw) and optionally, preservatives.

Lammerding et al. ("Quantitative Risk Assessment: An Emerging Tool for Emerging Foodborne Pathogens") teaches a system for modeling the health risks from eating contaminated

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food, including the ability to manipulate various parameters such as pathogen prevalence and concentration in raw material, temperature abuse in transportation and retail, consumer cooking preference, infectious dose and size of susceptible populations.

Wijtzes et al. ("A Decision Support System for the Prediction of Microbial Food Safety and Food Quality") teaches the development of a method to predict microbial food safety and quality.

FSIS[1] ("*Salmonella* Enteritidis Risk Assessment") teaches a risk assessment process which incorporates available data into a comprehensive quantitative model which characterizes the public health effects associated with the consumption of *Salmonella* Enteritidis-infected shell eggs and egg products, including data on the distribution chain as incorporated in the Shell Egg Processing and Distribution Module and the Egg Products Processing & Distribution Module.

Bidawid et al. ("Contamination of Foods by Food Handlers: Experiments on Hepatitis A Virus Transfer to Food and Its Interruption") teaches novel information concerning the rate of virus transfer to foods and a model for investigating the transfer of viral and other food-borne pathogens from contaminated hands to foods, as well as techniques for interrupting such transfer to improve food safety.

Bailar ("Ensuring Safe Food: An Organizational Perspective") teaches methods of making the U.S. food supply safer.

Maslanka et al. ("Foodborne Pathogen and Toxin Diagnostics: Current Methods and Needs Assessment from Surveillance, Outbreak Response and Bioterrorism Preparedness Perspectives") teaches that newer laboratory methods are needed for rapid detection of an etiological agent in the food supply so that prevention strategies can be implemented quickly to reduce the incidence of disease.

FoodNet ("FoodNet Annual Report 2000") summarizes the data collected through FoodNet's active surveillance sites in order to identify, control and prevent foodborne disease hazards.

Kleer et al. ("Importance of Predictive Microbiology for Risk Minimization in Food Production Process") teaches the application of mathematical models used for predictive microbiology at all stages of food production and distribution.

Koopman ("Responding to an Infection Transmission Emergency") is a PowerPoint™ presentation.

Scott ("The Food Industry's Response to Ensuring Food Security and Safety") is a PowerPoint™ presentation.

The following references, while not qualifying as prior art, are also of interest:

Pickett et al. (U.S. Patent 6,671,698) teaches a method of tracing an agricultural product including recording at least one of planting information, growing information, harvesting information, chemical information and weather information concerning a crop to form a data profile for a corresponding crop.

Pickett et al. (U.S. Patent 6,691,135) teaches a method of tracing an agricultural product including recording at least one of planting information, growing information, harvesting information, chemical information and weather information concerning a crop to form a data profile for a corresponding crop.

Hoffman et al. (U.S. Patent Application Publication 2003/0018513) teaches a system for benchmarking product sales information in a supply chain.

Hoffman et al. (U.S. Patent Application Publication 2003/0069774) teaches a system for distributor/supplier selection in a supply chain management framework.

Burk (U.S. Patent Application Publication 2003/0074250) teaches a system for collaborative forecasting in a supply chain management framework.

Hoffman et al. (U.S. Patent Application Publication 2003/0083947) teaches a system for governing a supply chain consortium in a supply chain management framework.

Curkendall et al. (U.S. Patent Application Publication 2003/0177025) teaches a system for agricultural data collection and management which provides quality assurance source verification data and performance tracking for agricultural items throughout the production cycle.

Morris (U.S. Patent Application Publication 2004/0078227) teaches a system for creating a longitudinal medical record for an injured person.

Cipra ("Hot Topics' Workshop Takes a Logistical Look at Biodefense") discusses the proceedings of a biodefense workshop on supply chain and logistics optimization with relation to bioterrorism.

National Research Council ("Making the Nation Safer: The Role of Science and Technology in Countering Terrorism") teaches the contributions that can be made by science and technology to countering terrorism.

Woo ("The Evolution of Terrorism Risk Modeling") teaches a more formal analytical methodology in terrorism risk management.

Bruemmer ("Food Biosecurity") evaluates and analyzes the threat of a bioterrorism attack on the U.S. food supply at every level of preparedness planning.

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Nganje et al. ("Terrorism and the Grain Handling System in Candad and the United States") examines the impact and consequences of an agro-terrorism attack on the grain transport and handling system in Canada and the United States.

Joppen ("Food Terror") examines the issue of food contamination by terrorist groups.

FSIS[2] ("Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods") teaches a risk assessment of foodborne listeriosis.

Lambert ("Statement of Dr. Charles Lambert before the Senate Committee on Governmental Affairs "Agroterrorism: The Threat to America's Breadbasket") teaches the work of the Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service (FSIS) in protecting agriculture against terrorist attacks.

Murano ("Perspectives on Food Safety") teaches remarks delivered by the Under Secretary for Food Safety.

AAAS ("Planning Effective Bioterror Responses") teaches computer models that suggest strategies for stopping disease outbreaks.

Golan et al. ("Traceability in the U.S. Food Supply: Economic Theory and Industry Studies") teaches that private sector food firms have developed a substantial capacity to manage the flow of inputs and products to improve efficiency, product differentiation, food safety and product quality.

Sholl ("Security in the Food Supply: Detection, Identification and Response") is a PowerPoint™ presentation.

CDC ("What is FoodNet?") teaches the Foodborne Diseases Active Surveillance Network (FoodNet), the principal foodborne disease component of the CDC's Emerging Infections Program (EIP).

National Academy of Sciences ("Countering Agricultural Bioterrorism") teaches an assessment of the vulnerability of U.S. agriculture to intentional threats.

Zebra Technologies ("Bar Coding and RFID: The Key to Traceability and Safety in the Foodservice Supply Chain") teaches that bar code and radio frequency identification (RFID) technologies can provide traceability and real-time control to meet customer and regulatory requirements while actually improving efficiency and profitability.

USDA ("National Inter-Agency Incident Management System (NIIMS) Operational System Description") teaches the capabilities of the NIIMS system.

Labuza ("Food Bio-Security: Case Studies in the Food Distribution Chain") is a PowerPoint™ presentation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke S. Wassum whose telephone number is 703-305-5706. The examiner can normally be reached on Monday-Friday 8:30-5:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John E. Breene can be reached on 703-305-9790. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

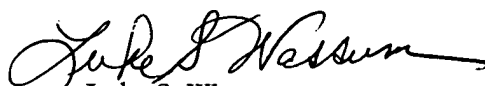
In addition, INFORMAL or DRAFT communications may be faxed directly to the examiner at 703-746-5658.

Customer Service for Tech Center 2100 can be reached during regular business hours at (703) 306-5631, or fax (703) 746-7240.

Applicant(s) should be aware that the examiner is currently scheduled to move to the new Alexandria campus in late October 2004. At that time, the new Tech Center 2100 main telephone number will be (571) 272-2100. The examiner's new telephone number has not yet been assigned. For up-to-date telephone contact information, please see www.uspto.gov, and select "Employee Locator" from under the Site Index.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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25 August 2004